

**M52010 OP AIR-PRO® OXYGEN**  
**M52010S RESPIRATORY PROTECTION MASK**  
 Personal Protective Equipment, Category III and Medical Device, Class I

### FEATURES & BENEFITS







- Filtering half mask, efficiency class FFP2 NR D developed to protect against solid and liquid aerosols
- Ultrasonic welding
- M52010S items are individually packed in a polybag

### Recommended use :

- Use in dusty environment
- To prevent against risky infectious diseases (According to national recommendations)

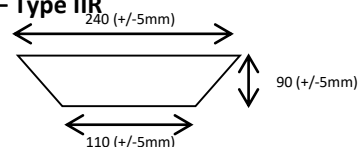


Using: 8 H

Item	M52010-LV M52010S-LV	M52010-BL M52010S-BL	M52010-PK M52010S-PK	M52010-YL M52010S-YL	M52010-GR M52010S-GR	M52010-WH M52010S-WH
<b>Colour</b>	Lavender 	Blue 	Pink 	Yellow 	Green 	White 

### PRODUCT DETAILS

Product name: **KOLMI - Op-Air Pro® Oxygen – Mask FFP2 NR D – Type IIR**  
 Product type: Single use, non-sterile  
 Inner/Outer layer: Spunbond 100% polypropylene  
 Filter: Meltblown 100% polypropylene  
 Nosepiece: Polypropylene and iron  
 Unit weight : 6,2 g (± 10%)  
 Origin : France



### EN 149:2001+A1:2009

Test	Required level	Laboratory	Report number	Date of Report	Average value
Paraffin Oil penetration	< 6 % after 120mg exposure	APAVE	20.0073.0021	15/05/2020	Compliant
NaCl penetration	< 6 % after 120mg exposure				Compliant
Facial leakage	≤ 11 % for at least 46 results over 50 ≤ 8 % for at least 8 arithmetic means over 10				Compliant
Air permeability inhalation 30 l/min	≤ 0,7 mbars				Compliant
Air permeability inhalation 95 l/min	≤ 2,4 mbars				Compliant
Air permeability exhalation 160 l/min	≤ 3 mbars				Compliant
Carbon dioxide content	< 1,0 %				Compliant
Flammability	Must not burn or continue to burn for more than 5 seconds after the withdrawal of the flame				Compliant

Protection (D) : protection against solid and liquid aerosols, combined with resistance higher to clogging tested with dolomite dust

**Annual observation according to module D - Reg (UE) 2016/425 done by APAVE**

NF EN 14683:2019

Test	Standard	Required level	Laboratory	Report number	Date of Report	Value
Bacterial Filtration Efficiency: BFE	EN 14683:2019	≥ 98% (Type IIR)	CENTEXBEL	20.00718.02	20/03/2020	99.9% min
DELTA P	EN 14683:2019	< 60 Pa/cm <sup>2</sup>	CENTEXBEL	20.00718.02	20/03/2020	46,3 Pa/cm <sup>2</sup> max
SPLASH	ISO 22609:2004	≥ 16 kPa	CENTEXBEL	20.00718.02	20/03/2020	Compliant
Cytotoxicity	ISO 10993-5	no cytotoxicity	NELSON	1030830-S01	20/03/2018	no cytotoxicity
Intracutaneous irritation test	ISO 10993-10	no irritation	NAMSA	231037	21/06/2017	no irritation
Sensitization	ISO 10993-10	no sensitization	NAMSA	231038	19/06/2017	no sensitization
Microbial cleanliness CFU/g	NF 11737:2018	≤30 cfu/g	MICROSEPT	1812006-15	14/04/2020	Compliant
Using time : BFE + Delta P	EN 14683:2014	≥ 98% (Type IIR) < 49 Pa/cm <sup>2</sup>	NELSON	961620-S01	10/05/2017	8h : > 99.9% 8h : < 37,00 Pa/cm <sup>2</sup>

### PRECAUTIONS FOR USE

The device should only be used on intact skin.

Their re-use or prolonged use can produce infection or cross-contamination.

After use, comply with the national regulations in force for the disposal of the device.

### CERTIFICATION & STANDARDS

Meet the requirements of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2016/425 on personal protective equipment.

Comply with the applicable harmonized standards EN 14683:2019 and EN 149:2001+A1:2009.

Manufactured under ISO 13485 and ISO 9001 certified systems.

### STORAGE

Normal conditions of conservation and storage: must not be exposed to humidity and sun, must be stored at a temperature between 5°C and 40°C.

Product life: 5 years.

### LOGISTICAL INFORMATION



#### Outer case specifications

#### Inner case specifications

Item	Size mm	Gross weight kg	QTY/pallet	Size mm	Packaging	QTY
M52010	560 x 260 x 270	4,3	36 cartons (6 layers of 6 cartons)	255 x 110 x 133	Bulk	10 boxes of 50 pieces
M52010S	560 x 260 x 270	4,8	36 cartons (6 layers of 6 cartons)	255 x 110 x 133	Individual bag	10 boxes of 50 pieces

M52010S items are individually packed in a polybag.